

产品编码 建立联系....

朱莉·“布兰迪”·斯图尔特
中心产品编码协调员
消费者安全官员，510(k) 工作人员
食品和药品管理局评估办公室
医疗器械和放射健康中心

Public Law 94-295
94th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.

May 28, 1976
[S. 510]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Medical Device
Amendments of
1976.
21 USC 301 note.

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1976".

(b) Whenever in this Act (other than in section 3(a)(1)(B)) an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be construed to be made to the section or other provision of the Federal Food, Drug, and Cosmetic Act.

21 USC 301.

1976年5月28日
医疗器械修正案
公法 94-295

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

Sec. 2. Regulation of medical devices.

"Sec. 513. Classification of medical devices into classes.

- "(a) Terms and uses.
- "(b) Classification; effective dates.
- "(c) Classification panel organization and operation.
- "(d) Classification.
- "(e) Classification change.
- "(f) Initiation, classification review, in device.
- "(g) Information.
- "(h) Definitions.

"Sec. 514. Performance standards.

- "(a) Provisions of standards.
- "(b) Initiation of a proceeding for a performance standard.
- "(c) Invitation for standards.
- "(d) Acceptance of certain existing standards.
- "(e) Acceptance of offer to develop standard.
- "(f) Development of standard by Secretary after publication of subsection (c) notice.
- "(g) Establishment of a standard.

"Sec. 515. Premarket approval.

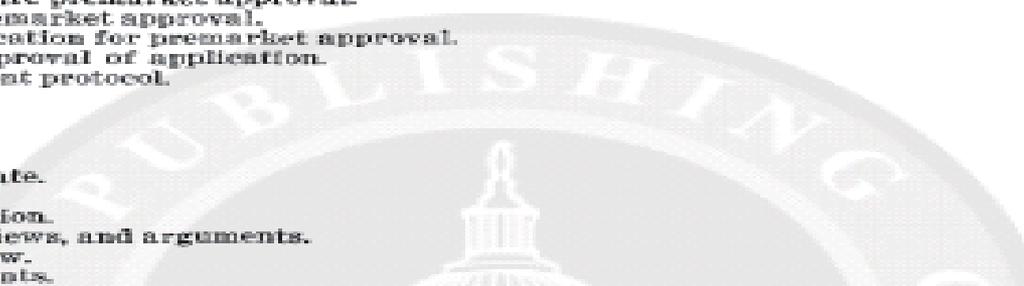
- "(a) General requirement.
- "(b) Regulation to require premarket approval.
- "(c) Application for premarket approval.
- "(d) Action on an application for premarket approval.
- "(e) Withdrawal of approval of application.
- "(f) Product development protocol.
- "(g) Review.
- "(h) Service of orders.

"Sec. 516. Banned devices.

- "(a) General rule.
- "(b) Special effective date.

"Sec. 517. Judicial review.

- "(a) Application of section.
- "(b) Additional data, views, and arguments.
- "(c) Standard for review.
- "(d) Finality of judgments.



联邦法规(CFR)

1978年5月28日的医疗器械修正案要求
并导致:

1700种通用器械的分类。

联邦法规(CFR)

第21卷第862部分-第892部分

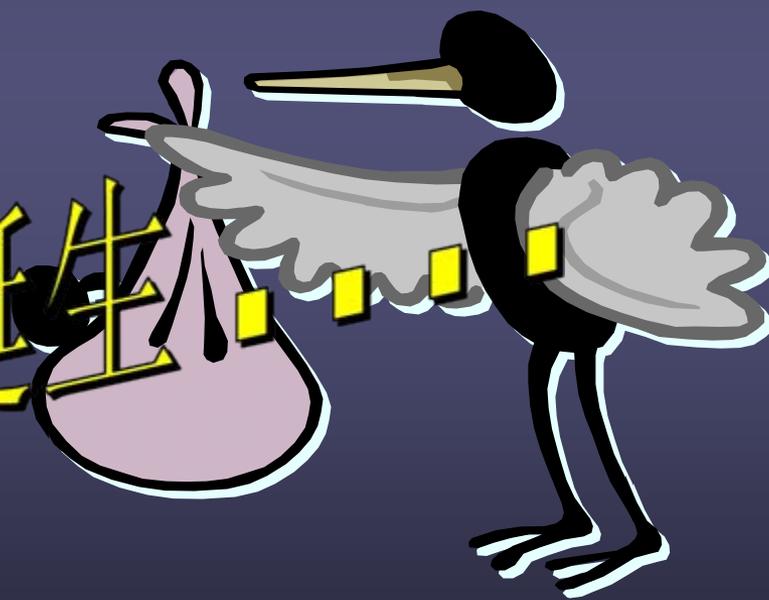


联邦法规(CFR) 第21卷第862部分-第892部分

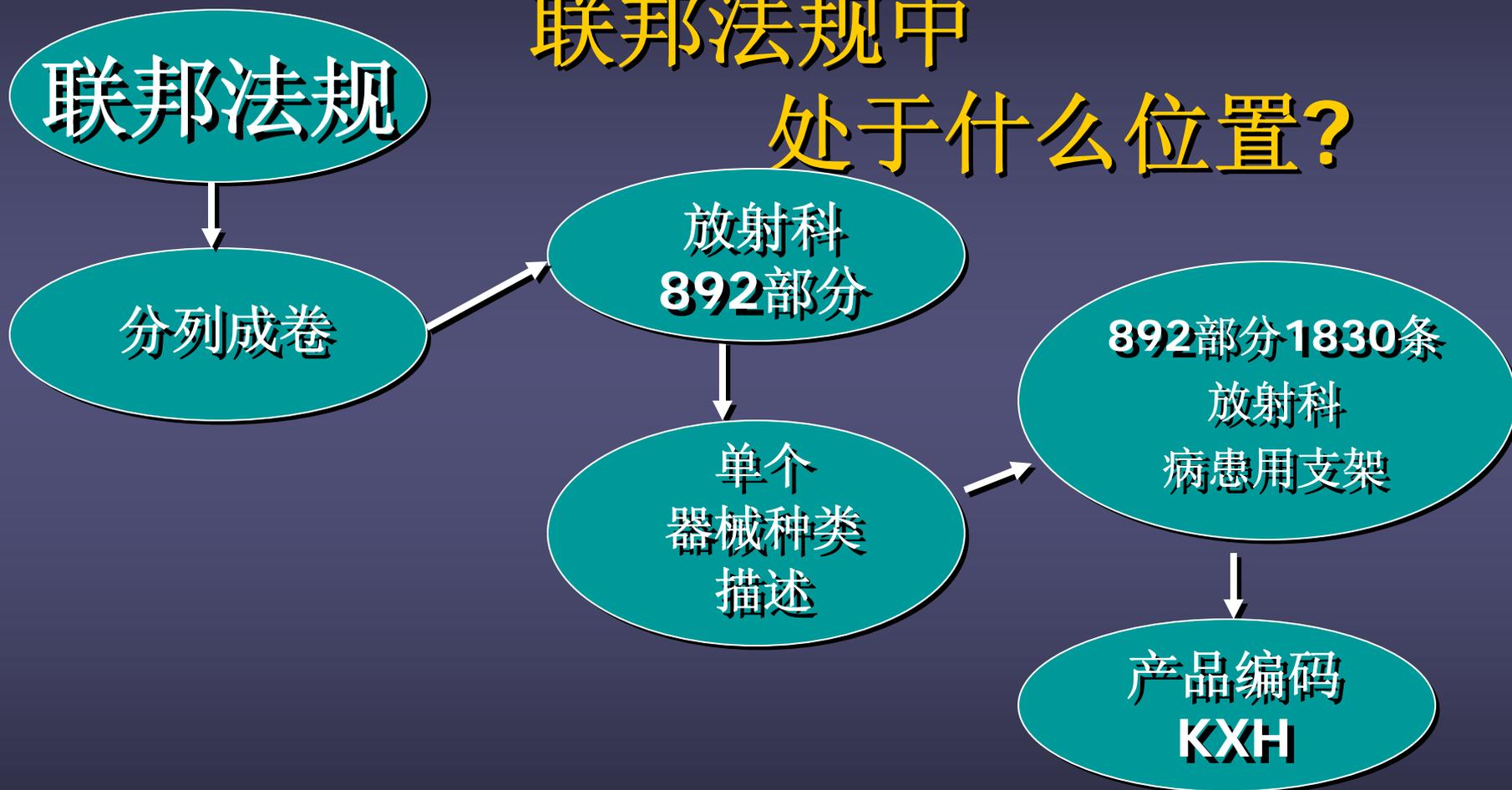
规定描述了1976年5月28日前存在的器械种类（修正案前器械）。

1976年5月28日
医疗器械
修正案
公法 94-295

产品编码诞生



产品编码在 联邦法规中 处于什么位置?





[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

产品编码: **KXH**

New Search	Back To Search Results
Product Registration Database	
Device:	Cradle, Patient, Radiologic
Regulation Description	Radiologic patient cradle.
Regulation Medical Specialty	Radiology
Review Panel	Radiology
Product Code	KXH
Submission Type	510(k) Exempt
Regulation Number	892.1830
Device Class	1
GMP Exempt?	No
Note: FDA has exempted almost all class I devices (with the exception of Reserved Devices) from the premarket notification	

目前的分类和 产品编码

各种器械通过上市前审议分类，
如**510(k)**、上市前批准（**PMA**）

新指定用途和新技术被设定新的产品编
码，置于最初的规定之下

联邦法规描述的修正案前 器械种类

872部分6865条 – 电动牙刷

电动牙刷由交流电或电池提供动力。该器械包括内装马达的手柄，以机械方式驱动一个刷子，旨在用于牙齿上。该器械的目的是从牙齿上去除牙菌斑和食物残渣，以减少牙齿腐蚀。

分类：第一类免除

产品编码信息：JEQ电动牙刷

相关规定：876部分6865条 第一类免除

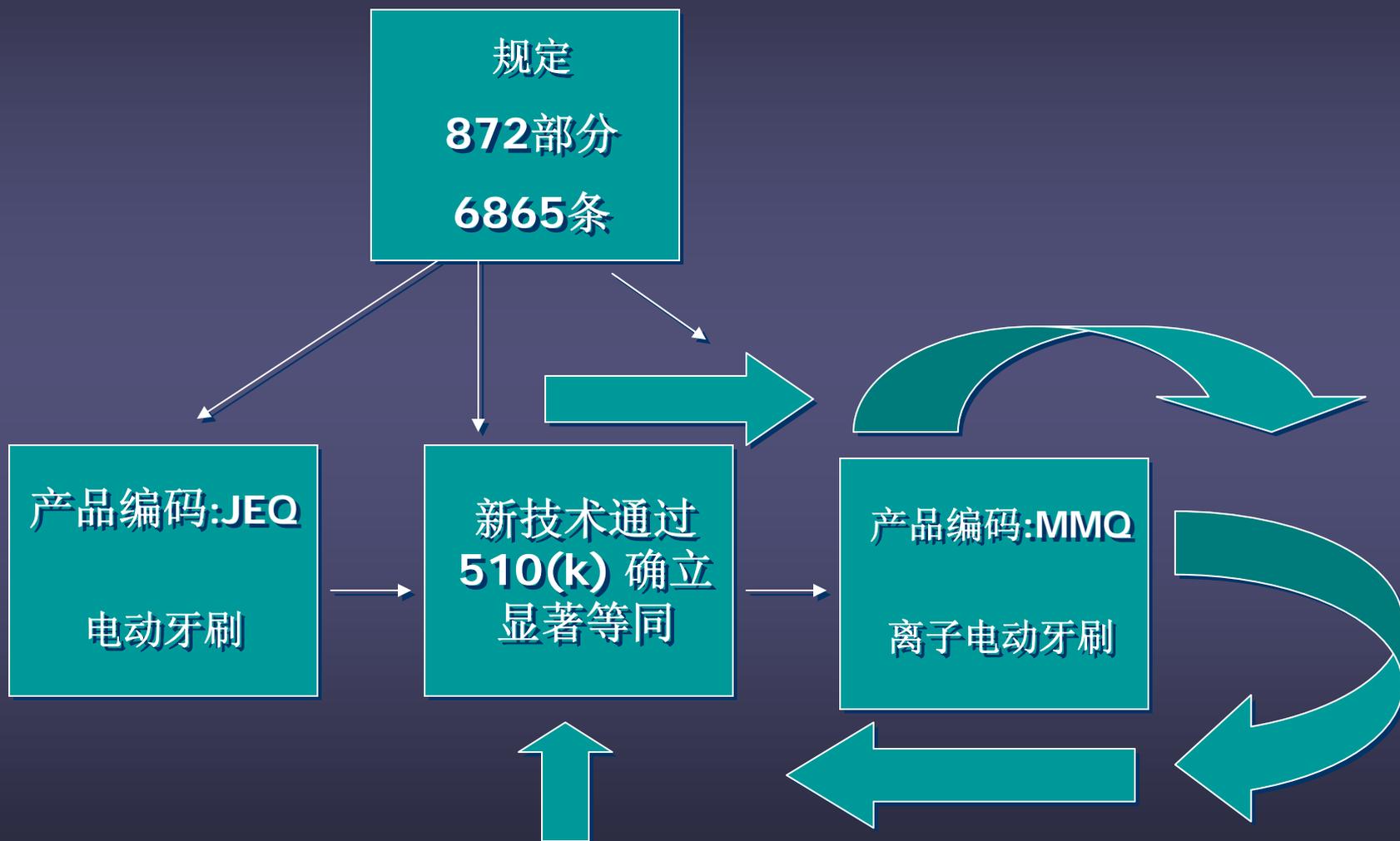
显著等同

新器械种类：离子电动牙刷
需要提交510(k)的新技术
510(k) 认定和修正案前器械
存在显著等同

产品编码信息：
MMQ 离子电动牙刷

相关规定：876部分第6865条
第一类器械免除

显著等同(SE)



产品编码对我来说为什么重要？

最终用来为510(k) 和上市前批准文件中的所有器械分类。

作为一种工具，产品编码：

- 用于器械登记和注册
- 用于搜索参照器械
- 用于搜索和通报不利事件
- 用于确定符合第三方审议标准的器械
- 用于器械进出口

产品编码对我来说为什么重要？

产品编码最终用于对所有510(k)和上市前批准文件中的器械进行分类





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

显著等同 (SE) 信函:

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Company ABC
c/o John Doe
123 Street Name
Somewhere, ST 99999

产品编码出现在所有显著等同信函上，并可以在互联网上获得

Re: K078522

Trade/Device Name: ABC Absorbable Gut Suture

Regulation Number: 21 CFR 878.4830

Regulation Name: Absorbable surgical gut suture

Regulatory Class: II

Product Code: GAK

Dated: May 1, 2007

Received: May 2, 2007

Dear Mr. Doe:

We have reviewed your Section 510(k) premarket notification of intent to market the

登记和注册

一家公司**只能**使用510(k)或者上市前批准申请获
准文件上的产品编码注册

除非是为下列器械登记注册

第一类免除器械

第二类免除器械

搜索参照器械



U.S. Food and Drug Administration



Department of
Health and
Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#)

Que

[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)



www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Search 510(k) Database [Help](#) [Privacy](#) [Feedback](#) [510\(k\)](#)

510K Number Type

Model Class 3/Appl. Revoc./L. Pre-Clas.

Applicant Name Third Party Reviewed

Device Name Expedited Review

Panel Product Code

Decision

Decision Date to

Sort by

For full-text search, select Go To Simple Search button

不利事件通报



U.S. Food and Drug Administration



Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#)

Qu

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, device reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.
- The on-line search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated quarterly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, inclusion of some reports may be delayed by technical or clerical difficulties.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Please be aware that reports regarding device safety may have been submitted to the manufacturer first. Searches of reports should be limited to the search criteria provided by the requester.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

Enter one or a combination of the MAUDE Search Values and select Search

Product Problem	<input type="text"/>	<input type="button" value="v"/>
Product Class	<input type="text"/>	<input type="button" value="v"/>
Brand Name	<input type="text"/>	510K Number <input type="text" value="K"/>
Manufacturer	<input type="text"/>	PMA Number <input type="text" value="P"/>
Event Type	<input type="text"/>	<input type="button" value="v"/> Product Code <input type="text"/>
Date Report Received by FDA (mm/dd/yyyy)	<input type="text" value="01/01/2008"/>	<input type="button" value="12 24"/> to <input type="text" value="08/29/2008"/> <input type="button" value="12 24"/>

For full-text search, select [Go To Simple Search](#) button

搜索符合第三方审批标准的器械种类

List of Devices for Third Party Review under the FDA Modernization Act of 1997 - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm?panel=SU#TopPage>

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4

Section No.	Regulation Name Product Code / Device Name	Relevant Guidance/Standard
878.4040	SURGICAL APPAREL	Text PDF PDF
	MSH - Respirator, Surgical	
	FXX - Mask, Surgical	Pilot
	FXY - Hood, Surgical	Pilot
	FYA - Gown, Surgical	Pilot
	FYB - Gown, Patient	Pilot
	FYC - Gown, Isolation, Surgical	Pilot
878.4200	INTRODUCTION/DRAINAGE CATHETER AND ACCESSORIES	General Guidance
	OAJ - Catheter, Drainage, Intraoral/Extraoral	
878.4350	CRYOSURGICAL UNIT AND ACCESSORIES	
	FAZ - System, Cryosurgical, Liquid Nitrogen, For Urology	Pilot
	GEH - Unit, Cryosurgical, Accessories	Pilot
878.4370	SURGICAL DRAPE AND DRAPE ACCESSORIES	
	MMP - Cover, Barrier, Protective	Pilot
	ERY - Drape, Surgical, Ent	Pilot
	EYX - Drape, Pure Latex Sheet, With Self-Retaining Finger Cot	Pilot

Local intranet 11:08 AM

分类数据库

FDA > CDRH > Product Classification Database Search - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> Go

FDA U.S. Food and Drug Administration Department of Health and Human Services
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#) [Questions?](#)

 [510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [DMA](#) | [Classification](#) | [CLIA](#) | [IR Titration](#) | [Agency Fees](#) | [Z/S](#) | [Submissions](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Search Classification Database [Help](#) | [Download Files](#) | [More About Classification](#)

Device Product Code

Review Panel Submission Type

Regulation Number Ther. Prod. / Lig. File

Sort By Device Name (A-Z) Device Class

For full-text search, select [Go To Simple Search](#) button

50 **Records per Report Page**

Database Updated 08/06/2008

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

start | 9 Microsof... | pro codes 2... | Microsoft O... | 5 Internet... | Local intranet | 11:16 AM

产品编码相关内容

[New Search](#)

[Back To Search Results](#)

Product Classification Database

Device	Elisa, Antibody, West Nile Virus
Regulation Description	West Nile virus serological reagents.
Definition	The west nile virus elisa is intended for the detection of igg and igm antibodies to west nile virus. Specimens may be serum or cerebral spinal fluid from symptomatic patients.
Regulation Medical Specialty	Microbiology
Review Panel	Microbiology
Product Code	NOP
Submission Type	510(k)
Regulation Number	866.3940
Device Class	2
GMP Exempt?	No
Guidance Document	

分类数据库

提供:

通往标准的链接;

通往相关指导文件的链接;

产品编码定义以及指定用途;

详细说明; 以及

第三方审批资格



朱莉“布兰迪”斯图尔特
中心产品编码协调员

电邮: **julie.stuart@fda.hhs.gov**

电话: **240-276-4020**

信息高速公路

食品和药物管理局主页: www.fda.gov

器械咨询: www.fda.gov/cdrh/devadvice

搜索美国联邦注册:

www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm

美国联邦法规 (CFR):

www.fda.gov/cdrh/devadvice/365.html

美国联邦食品、药品和化妆品法:

www.fda.gov/opacom/laws/fdcact/fdctoc.htm

信息高速公路

医疗器械和放射健康中心
公开检索数据库:

www.fda.gov/cdrh/databases.html

这个网站包含了超过15个FDA
公开检索数据库

510k 显著等同决策过程

指导 & 流程图

www.fda.gov/cdrh/k863.html